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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,969	12/14/2001	Richard A. Pittner	0401-UTL-0	7314

28381 7590 11/23/2005

ARNOLD & PORTER LLP
ATTN: IP DOCKETING DEPT.
555 TWELFTH STREET, N.W.
WASHINGTON, DC 20004-1206

EXAMINER	
LI, RUIXIANG	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 11/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,969	PITTNER ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,8 and 33-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 8, 33-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/11/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The Request filed on 10/11/2005 for Continued Examination (RCE) under 37 CFR 1.114 of Application 10/016,969 is granted. An action on the RCE follows.

The amendment filed on 10/11/2005 has been entered. Claims 1, 8, 33-41, 43-47, 51-54 have been amended. Claims 55-63 have been added. Claims 1, 8, and 33-63 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Withdrawn Objections and/or Rejections

The rejection of claims 1, 33, 38, 42, 48-50, and 52-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Morley et al (*Life Sci.* 41:2157-2165, 1987) is withdrawn for purpose of clarity because these claims have been rejected under 35 U.S.C. 102(b) as being anticipated by Yoshinaga et al. (*Am. J. Physiol.* 263:G695-701, 1992) or Okada et al. (*The Endocrine Society 75th Annual Meeting Prograpm & Abstract*, page 180, Abstract 520B, 1993).

The rejection of claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morley et al (*Life Sci.* 41:2157-2165, 1987), and further in view of Naslund et al. (Int. J.

Obes. Relat. Metab. Disord. 23:304-311, 1999) is withdrawn for the purpose of clarity because the claim is already rejected over Okada et al., and further in view of Naslund et al. (Int. J. Obes. Relat. Metab. Disord. 23:304-311, 1999).

Information Disclosure Statement

The information disclosure statement filed on 10/11/2005 has been considered by the Examiner and a signed copy has been attached to this office action.

Claim Rejections under 35 USC § 112, 1st paragraph

(i). Claims 1, 8, 33-46, and 48-63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method comprising peripherally administering an effective amount of a PYY or PYY(3-36) to a subject, does not reasonably provide enablement for the claimed invention commensurate in scope with the claims (see below). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the claims.

The factors considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex*

Parte Forman, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claims 1, 8, 33-46, and 48-63 are are drawn to methods of administering to a subject a PYY or a PYY agonist. The specification defines a PYY agonist as any compound which elicits an effect of PYY to reduce nutrient availability (page 5, lines 24-25). Such agonists can comprise a polypeptide having a functional domain, an active fragment of PYY, a chemical, or a small molecule. PYY agonists may be peptide or non-peptide compounds, and may include PYY agonist analogs, which refer to any compound structurally similar to a PYY that have PYY activity (page 6, lines 3-6). While the amended claims recite a limitation, "wherein the PYY agonist is a peptide", the scope of the claims are still broad because such a limitation does not provide any structural feature of the genus of PYY agonists. The claims are drawn to a method comprising administration of a genus of structurally undefined PYY agonists. However, the specification merely discloses two compounds: PYY and PYY (3-36), and fails to provide the characteristic structure that is critical for the function of PYY and fails to provide sufficient guidance on how to make such PYY agonists.

The prior art teaches that peripheral administration of PYY or PYY3-36 inhibits pancreatic exocrine and gastric acid output in mongrel dogs (Yoshinaga et al., *Am. J. Physiol.* 263:G695-701, 1992), reduces body weight in 12-week-old mice (Morley et al., *Life Sci.* 41:2157-2165, 1987), and reduces high fat diet intake in male Sprague-Dawley

rats (Okada et al., *The Endocrine Society 75th Annual Meeting Programpm & Abstract*, page 180, Abstract 520B, 1993). The prior art does not provide teachings for the broad genus of PYY agonists. U. S. Patent Nos: 5,574,010, 5,604,203, 5,696,093, and 6,046,167 describe PYY agonists. However, these U. S. Patents do not teach the PYY agonists in the context of reducing nutrient availability, food intake or body weight. The PYY agonists were taught for entirely different purposes, such as inhibiting proliferation of pancreatic tumors in U.S. Patent No. 5,574,010; treating nasal congestion in U.S. patent No. 5,696,093; controlling cell proliferation, nutrient transport, lipolysis, and intestinal water and electrolyte secretion in U. S. Patent No. 5,604,203. Moreover, the agonists are determined based upon the competitive binding assay in the presence of ^{125}I-PYY. An antagonist may bind the PYY receptor; but it does not make the antagonist a PYY agonist.

Other than the methods of administering to a subject a PYY or a PYY agonist, PYY3-36, the specification fails to provide sufficient guidance and/or working examples for an artisan to practice the instantly claimed methods. In view of the complexity of the nature of PYY-related compounds, it is unpredictable whether a compound that is related to PYY would work in the same manner as that of PYY. For example, PYY(6-36) and PYY(13-36), when peripherally administered, do not inhibit gastric acid secretion or pancreatic exocrine secretion (see, e.g., Yoshinaga et al., *Am. J. Physiol.* 263:G695-701, 1992). Take another example, U.S. Patent No. 5,574010 teaches a PYY agonist, NPY (column 3). However, from the instant disclosure, NPY is not active in inhibiting

food intake (Table 1 and Figure 1). Likewise, there is also a scope of enablement issue for the genus of agonists of GLP-1, an exendin, and an amylin, which are recited in claim 51. Therefore, it would require undue experimentation for one skilled in the art to make the genus of PYY agonists and to use the claimed agonists commensurate in scope with the claims.

(ii). Response to Applicants' argument

Beginning at the bottom of page 7 of Applicants' response filed on 10/11/2005, Applicants argue that PYY agonists are set forth in the specification. Applicants submit that SEQ ID NO: 2 and SEQ ID NO: 3 set forth PYY and PYY[3-36], respectively. Additionally, PYY agonists are provided in Table 1, on page 10, and are defined in the specification. Furthermore, other PYY agonists were known in the art at the time of filing. Applicants further submit that the specification provides methods for determining whether a PYY agonist is effective in the claimed methods. Applicants, citing MPEP and case law, argue that the office has not provided objective evidence that the known PYY agonists or PYY agonists analogues would not function in the methods as claimed.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the reasons set forth immediately above. In addition, since the instant claims do not recite a structural limitation for the genus of PYY agonists administered in the methods, the PYY agonists encompass more than the PYY agonists taught in the prior art cited by Applicants.

Claim Rejections under 35 USC § 112, 1st paragraph, Written Description

(i). Claims 1, 8, 33-46, and 48-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

Claims 1, 8, 33-46, and 48-63 are drawn to methods of administering to a subject a PYY or a PYY agonist. The specification defines PYY as a peptide YY polypeptide obtained or derived from any species, and defines PYY agonist as any compound which elicits an effect of PYY to reduce nutrient availability (page 5, lines 24-25). Thus, the claims are drawn to a method comprising administration of a genus of structurally undefined PYY agonists.

The specification fails to provide any critical structural feature to adequately describe the genus of PYY agonists that may be administered in the claimed method. The

specification merely discloses two compounds, a human PYY of SEQ ID NO: 2 and PYY (3-36) of SEQ ID NO: 3, which are not sufficiently representative of the claimed genus of PYY agonists. There is no defined relation between function and structure of the PYY agonists. There is even no identification of any particular portion of the structure that must be conserved. Likewise, claim 51 recites GLP-1, an exendin, an amylin, and their agonists. The specification does not provide a defined relation between function and structure of the agonists. There is no identification of any particular portion of the structure that must be conserved for these agonists. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the genus of PYY agonists and the genus of agonists of a GLP-1, an exendin, and an amylin.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of the PYY agonists, and therefore conception is not achieved until reduction to practice has occurred. Therefore, only the method of administering PYY and PYY(3-36),

but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph.

(ii). Response to Applicants' argument

Beginning at the bottom of page 9 of Applicants' response filed on 10/11/2005, Applicants argue that SEQ ID NO: 2 and SEQ ID NO: 3 set forth PYY and PYY[3-36], respectively. Additional PYY agonists and PYY agonist analogs are described in the specification and cited references, and assays are set forth for determining whether a PYY agonist or PYY agonist analogues is effective in the claimed methods. Applicants, citing case law, submit that Applicant is not required to re-describe that which is already known or readily determined by known procedures.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. The Examiner does not take issue with the case law and agrees with the Applicants that what is known in the art need not be disclosed in detail. However, claims 1, 8, 33-46, and 48-63 are drawn to methods of administering to a subject a PYY or a PYY agonist. The specification defines PYY as a peptide YY polypeptide obtained or derived from any species, and defines PYY agonist as any compound which elicits an effect of PYY to reduce nutrient availability (page 5, lines 24-25). Thus, the claims are drawn to a method comprising administration of a genus of structurally undefined PYY agonists. The specification merely disclose a human PYY of SEQ ID NO: 2 and a PYY agonist, PYY[3-36] of SEQ ID NO: 3 and fails to provide any

critical structural feature to adequately describe the genus of PYY agonists that may be administered in the claimed method. Table 1 apparently lists a human PYY and a PYY agonist, PYY[3-36], which are active in inhibiting food intake when peripherally administered. The prior art does not teach any other PYY agonists in the context of reducing nutrient availability, food intake or body weight. The prior art does not provide compensatory structural or correlative teachings to enable one skilled in the art to identify the encompassed PYY agonists being identical to those instantly claimed. Moreover, assays for determining whether a PYY agonist or PYY agonist analogues is effective in the claimed methods is not equivalent to methods of making PYY agonists because such an assay merely screens for a compound with certain activity, but does not provide any structural feature of the genus of PYY agonists administered in the claimed methods.

Claim Rejections under 35 USC § 112, 2nd paragraph

Claims 1, 8, 33-51, 54, and 56-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 8, 34-41, 52-54 are indefinite because each claim recites a limitation, "desirous of reducing caloric efficiency". It is unclear how such a limitation, which represents a mental process, limits the subject recited in the claims. Claims 33, 42, 47-51, and 63 are rejected as dependent claims..

Claims 8, 33-36, 43-51, 54, and 56-63 indefinite because they recite a limitation, "a peripheral parenteral route". Neither the specification nor the art define the term unambiguously, rendering the claims indefinite.

At the middle of page 10 of Applicants' response filed on 10/11/2005, Applicants argue that the phrase "a subject desirous of" is not indefinite. Applicants submit that the specification describes "any subject...who needs or wishes to reduce body weight" and a person of ordinary skill would understand the phrase in light of the specification.

Applicants' argument has been fully considered, but is not deemed to be persuasive because the instant claims recite a subject, which includes, for example, a mouse. It is unclear how a person of skilled in the art could determine whether a mouse wishes or desires to be treated with PYY or a PYY agonist.

Claim Rejections Under 35 U. S. C. § 102 (b)

(i) Claims 1, 8, 33-42, 47-49, 52-60, and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshinaga et al. (*Am. J. Physiol.* 263:G695-701, 1992).

Yoshinaga et al. teach a method of inhibiting pancreatic exocrine and gastric acid output comprising peripheral administration (intravenous infusion; see Experimental Design at page G696) to a subject (a mongrel dog; page G695, right column, under animal preparation) 200, 400, 800 pmol/kg/h (equivalent to about 20, 40, and 80 μg/kg/day,

respectively; molecular weight of PYY=4310) of peptide YY and a PYY agonist, PYY3-36 (see, e.g., Abstract, page G696, left column, Table 3, page G697). Since Yoshinaga et al. teach a method of administering to a subject the same agent (PYY or PYY agonist) in the same dose range by the same route of administration as that of the instantly claimed method, the intended uses and properties of the PYY or PYY agonist recited in the claims are inherent to the method taught by Yoshinaga et al. Thus, the reference of Yoshinaga et al. meets the limitations of claims 1, 8, 33-42, 47-49, 52-60, and 62.

Response to Applicants' argument

At page 11 of Applicants' response filed on 10/11/2005, Applicants argue that Yoshinaga et al. do not teach, expressly or inherently, each element recited in the claims. Applicants argue that the claimed methods require administration of an amount of a PYY or a PYY agonist effective to reduce caloric efficiency, nutrient availability, appetite, food intake, body weight or body weight gain, or increase weight loss. Applicants submit that the effectiveness of a PYY or PYY agonist on these functional activities was not measured in the study of Yoshinaga et al.

Applicants' argument has been fully considered, but is not deemed to be persuasive because Yoshinaga et al. teach a method of inhibiting pancreatic exocrine and gastric acid output, which are necessarily linked to other properties of PYY or PYY agonists, such as caloric efficiency, nutrient availability, appetite, food intake, or weight (see

bottom of the instant specification). Moreover, since Yoshinaga et al. teach a method of administering to a subject the same agent (PYY or PYY agonist) in the same dose as that of the instantly claimed method, the intended uses and properties of the PYY or PYY agonist recited in the claims are inherent to the method taught by Yoshinaga et al. The property or functional activity is inherent to the structure of a molecule because it is well established that a property or function of a molecule depends upon its structure. It is noted that recognition by a person of ordinary skill in the art is not required to show anticipation by inherency (*Schering Corp. v. Geneva Pharmaceuticals, Inc.,* No. 02-1540 (Fed. Cir. Aug. 1, 2003)).

At the 1st paragraph of page 12 of Applicants' response filed on 10/11/2005, Applicants argue that the Examiner has taken two complex physiologic responses and linked them without presenting any evidence that they are absolutely and always linked. Applicants argue that the variation of PYY and PYY3-36 in various assays reported by Yoshinaga et al. and disclosed by the inventor supports the assumption that inhibition of gastric acid and pancreatic exocrine secretion of Yoshinaga et al. are not necessarily and always linked to the reduction in nutrient availability, caloric efficiency, food intake and/or body weight of the instant invention.

Applicants' argument has been fully considered, but is not deemed to be persuasive because a property of a molecule, e.g., e.g., PYY or PYY3-36, is inherent to its structure. The variation in measuring a property of a molecule does not affect such

inherency. Moreover, both PYY and PYY3-36 have the same biological effects, albeit some difference in their effectiveness.

At the 2nd paragraph of page 12 of Applicants' response filed on 10/11/2005, Applicants argue that Yoshinaga et al. cannot render unpatentable by inherency the subject population of claims 1, 8, 33-42, 47-54 and new claims 56-62, i.e., subjects desirous or in need of reducing caloric efficiency, nutrient availability, body weight, food intake or appetite.

Applicants' argument has been fully considered, but is not deemed to be persuasive because Yoshinaga et al. teach a method of inhibiting pancreatic exocrine and gastric acid output comprising peripheral administration to a subject, a mongrel dog, which was in need of such a treatment; otherwise such a treatment would not have been performed by Yoshinaga et al. It is noted that claims 50, 51, and 61 are not rejected under this rejection.

(ii). Claims 1, 8, 33-42, 47-50, and 52-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Okada et al. (*The Endocrine Society 75th Annual Meeting Prograpm & Abstract*, page 180, Abstract 520B, 1993).

Okada et al. teach a method of reducing high fat diet intake comprising peripherally administering PYY to male Sprague-Dawley rats at the doses of 1, 10, 20, and 40 nmol

(equivalent to about 4.3, 43, 86, and 172 μg, respectively; molecular weight of PYY=4310). Okada et al. further teach that PYY is a satiety factor for fat meal. Assuming the body weight of the rats are 200 g to 400 g, the dose of 4.3 ug PYY administered to a rat would be about 10.8 to 22 μg/kg. Thus, the dosage taught by Okada et al. reads on the dose range of PYY recited by the instant claims. It is noted that PYY can be considered as a PYY agonist in view of the instant disclosure (page 5 of the specification). Since Okada et al. teach a method of administering to a subject the same agent (PYY) in the same dose range by the same route of administration as that of the instantly claimed method, all the intended uses and properties of the PYY or PYY agonist recited in the claims are inherent to the method taught by Okada et al. et al. Thus, the reference of Okada et al. meets the limitations of claims 1, 8, 33-42, 47-50, and 52-62.

Response to Applicants' argument

Beginning at the bottom of page 13 of Applicants' response filed on 10/11/2005, Applicants, citing case law, argue that Okada et al. does not teach, expressly or inherently, each element recited in the claims. Okada et al. does not teach, expressly or inherently, reducing intake of or appetite for food which comprises both high and low fat food of claims 34 and 36, nor does it teach reducing intake of or appetite for non-high fat food of claims 8 and 35. Okada cannot anticipate, expressly or inherently, the claimed subject population.

Applicants' argument has been fully considered, but is not deemed to be persuasive because Okada et al. teach a method of administering to a subject the same agent (PYY) in the same dose as that of the instantly claimed method, all the intended uses and properties of the PYY or PYY agonist recited in the claims are inherent to the method taught by Okada et al. et al.

Moreover, claims 34 and 36 merely recite a preamble, "a method of reducing food intake" and "a method of reducing appetite". Okada et al. teach a method of reducing high fat diet intake. Okada et al. also teach that PYY is a satiety factor for fat meal. The teachings of Okada et al meet the limitations of claims 34 and 36. Claims 8 and 35 recite a preamble, "a method of reducing non-high fat food intake" and "a method of reducing appetite for non-high fat food". "Non-high fat food" still encompasses "medium fat food" or "fat food". Since Okada et al. teach that PYY is a satiety factor for fat meal, the reference of Okada et al. meets the limitations of claims 8 and 35. Furthermore, Okada et al. teach a method of reducing high fat diet intake comprising peripherally administering PYY to male Sprague-Dawley rats, which was in need of such a treatment; otherwise such a treatment would not have been performed by Okada et al.

Claim Rejections Under 35 U. S. C. §103 (a)

(i) Claims 44, 46, and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al. (*The Endocrine Society 75th Annual Meeting Prograpm & Abstract*, page 180, Abstract 520B, 1993).

Okada et al. teach a method of reducing high fat diet intake comprising peripherally administering PYY to male Sprague-Dawley rats at the doses of 1, 10, 20, and 40 nmol (equivalent to about 4.3, 43, 86, and 172 μg, respectively; molecular weight of PYY=4310). Okada et al. further teach that PYY is a satiety factor for fat meal. Assuming the body weight of the rats are 200 g to 400 g, the dose of 4.3 ug PYY administered to a rat would be about 10.8 to 22 ug/kg. Thus, the lowest dosage taught by Okada et al. reads on the dose range of PYY recited by the instant claims. It is noted that PYY can be considered as a PYY agonist in view of the instant disclosure (page 5 of the specification).

Okada et al. do not teach administering PYY to a human subject. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to administer PYY to a human subject to reduce appetite or food intake with a reasonable expectation of success in view of the teachings of Okada et al. on the rats. It is a logical and obvious step for one of skill in the art to treat a human subject after a drug is tested successfully in an animal model.

(ii) Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al., as applied to claims 1, 8, 33-42, 47-50, and 52-62, in view of Naslund et al. (Int. J. Obes. Relat. Metab. Disord. 23:304-311, 1999).

Okada et al. teach a method of reducing high fat diet intake comprising peripherally administering PYY to male Sprague-Dawley rats as applied to claims 1, 8, 33-42, 47-50, and 52-62, respectively. Okada et al. do not teach administration of GLP-1, an exentin, an amylin or their agonists in combination with PYY.

Naslund et al. teach that intravenous infusion of GLP-1 suppresses energy intake and appetite in obese men (Abstract).

Therefore, It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method taught by Okada et al. to administer GLP-1 in combination with PYY with a reasonable expectation of success. One would have been motivated to do so because GLP-1 has been clearly shown to decrease feelings of hunger and reduces energy intake as taught by Naslund et al. and the combination of GLP-1 with PYY would be expected to be successful, since they are both taught to have the same effect.

Response to Applicants' argument

At the 3rd paragraph of page 15 of Applicants' response filed on 10/11/2005, Applicants review case law with respect to establishing a prima facie case of obviousness under 35 U.S.C.§ 103, with which the Examiner does not take an issue.

Beginning at the bottom of page 15 of Applicants' response filed on 10/11/2005, Applicants argue that Okada et al do not teach GLP-1, an exendin, an amylin, their agonists, or any combination thereof, and do not teach the co-administration of a PYY or a PYY agonist with any other compounds. Naslund does not cure the deficiencies of Okada et al. Applicants further submit Naslund does not teach or suggest administration of PYY, PYY agonists, or co-administration of GLP-1.

Applicants' argument has been fully considered, but is not deemed to be persuasive because the combined teachings of Okada et al with Naslund et al. make the instantly claimed invention obvious. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method taught by Okada et al. to administer GLP-1 in combination with PYY with a reasonable expectation of success. One would have been motivated to do so because GLP-1 has been clearly shown to decrease feelings of hunger and reduces energy intake as taught by Naslund et al. and the combination of GLP-1 with PYY would be expected to be successful, since they are both taught to have the same effect. Moreover, it's noted that if each reference alone meets the limitation of claim 51, the rejection would be 102, not 103 any more. Thus, Applicants' criticism on each reference is invalid.

Claim objections —Minor Informalities

Claims 8, 34-36, 43-46, and 56-58 are objected to because each claim recites "peripheral parental". Two adjectives cannot be used consecutively. Appropriate correction is required.

Conclusion

No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li

Ruixiang Li, Ph.D.
Primary Examiner
November 16, 2005